

REMARKS

The Applicants initially note that the Examiner has allowed Claims 1, 2, and 5. The Applicants have amended the Specification to update the cross-reference to related applications and to include two sequence identification numbers that were inadvertently omitted from the application as filed. The Applicants have also amended Claims 3, 4, and 32, and added new Claims 48-51 in order to more particularly point out and distinctly claim the subject matter that the Applicants regard as their invention. Support for the amendments to the claims and for the new claims can be found throughout the Specification, including in the original claims. Further support for the amendment to Claim 3 can be found on Page 17, lines 14-18, and on Page 23, lines 8-11 of the original Specification. Further support for the amendment to Claim 4 can be found on Page 30, lines 9-10 of the original Specification. Further support for newly added Claims 48-51 can be found on Page 5, lines 8-22 of the original Specification. Claim 32 has been rewritten to include the features of withdrawn Claim 6. Original Claims 1, 2, 5, and 33-42; newly amended Claims 3, 4, and 32; and newly added Claims 48-51 remain for consideration. No new matter has been entered.

The Present Application Complies with the Sequence Rules

The Examiner has pointed out that the specification does not comply with 37 CFR 1.821-1.825 of the Sequence Rules and Regulations. In short, two sequences disclosed on Page 43 of the Specification were not originally included in the Sequence Listing, or identified in the Specification by SEQ ID NO.

In full compliance with 37 CFR 1.821-1.825 of the Sequence Rules and Regulations, the Applicants submit herewith a new Sequence Listing including the two sequences that were disclosed on Page 43 of the Specification, but were inadvertently omitted from the Sequence Listing. In addition, the Applicants have amended Page 43 of the Specification to include the SEQ ID NOs. for these two sequences.

Rejections under 35 USC § 112

The Examiner has rejected Claim 4 under 35 USC § 112 paragraphs 1 and 2.

The Examiner has also rejected Claims 32-42 under 35 USC § 112 paragraph 2.

The Examiner asserts that Claim 4 is indefinite under 35 USC § 112 paragraph 2 because the Applicants have not provided a definition for the term "stringent conditions" and further asserts that it is unclear what sequences are excluded from this claim. Although determining that the Specification provides adequate written description for an isolated nucleic acid molecule comprising SEQ ID NO: 1 and an isolated nucleic acid molecule encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, the Examiner also asserts that in the absence of a recitation of clear hybridization conditions, Claim 4 does not meet the written description provision.

In addition, the Examiner asserts that Claims 32-42 are indefinite because Claim 32 depends from withdrawn Claim 6 and thereby, it is unclear what the instant claim encompass. Finally, the Examiner points out that the term "immunogenic composition" of Claim 32 lacks antecedent basis.

The Applicants respectfully traverse the Examiner's rejection. The Applicants have amended Claims 4 and 32 (from which Claims 33-42 depend) to more particularly point out and distinctly claim the subject matter which the Applicants regard as their invention. In addition, the Applicants respectfully point out that the present invention is not directed towards human, murine, or rat RANKLs. Newly amended Claim 4 therefore, does not include naturally occurring human, murine, or rat RANKLs. Indeed, the Applicants have specifically stated that such RANKLs were known prior to the filing of the present application (see, bridging paragraph between Page 2 and 3 of the instant Specification).

In view of the above and foregoing withdrawal of the rejections under 35 USC § 112 paragraphs 1 and 2 is respectively solicited.

The Present Invention is Novel

The Examiner has rejected Claim 3 under 35 U.S.C. § 102 (e) as being anticipated by Boyle *et al.* [U.S. Patent No. 6,316,408 B1] asserting that Boyle *et al.* teach the human OPG binding protein (*i.e.*, human RANKL, OPGL) that the Examiner asserts is 91.3% identical to a polynucleotide sequence encoding the polypeptide of SEQ ID NO: 2. More specifically the Examiner asserts that because Claim 3 recites “a complement” versus “a full complement” the polynucleotide sequence of Boyle is encompassed by Claim 3.

The Applicants respectfully traverse the Examiner’s rejection. The Applicants have amended Claim 3 to more particularly point out and distinctly claim the subject matter which the Applicants regard as their invention. The Applicants believe that the amendment obviates the Examiner’s rejection.

In view of the above and foregoing withdrawal of the rejections under 35 U.S.C. § 102 (e) is respectfully solicited.

If any additional fees are required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 19-0365.

The Applicants believe that the next step in the prosecution of this Application should be in the form of a Notice of Allowance and such action is respectfully solicited.

If the Examiner should have any questions regarding this Amendment and/or patent Application, she is encouraged to contact the undersigned attorney.

Schering-Plough Corporation
2000 Galloping Hill Road
Patent Department, K-6-1,1990
Kenilworth, NJ 07033
Tel: (908) 298-2194
Fax: (908) 298-5388

Respectfully submitted,


Michael D. Davis
Attorney for Applicants
Reg. No. 39,161
February 13, 2008